

MLB

Conflicts of Interest in Vaccine Policy Making
Majority Staff Report
Committee on Government Reform
U.S. House of Representatives
August 21, 2000

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Section I

Introduction

In August 1999, the Committee on Government Reform initiated an investigation into

December 12, 1997. They were:

a.) ~~Dr. Neal Halsey:~~ Dr. Halsey has been one of the leading investigators and advocates in the area of vaccines. In addition to numerous grants and contracts from different vaccine manufacturers, Dr. Halsey has received frequent reimbursements for travel expenses and honoraria from companies such as Merck. Importantly, at the time of the "RotaShield" approval meeting, Dr. Halsey was seeking start-up funds from most of the vaccine manufacturers for the establishment of an institute for vaccine safety at Johns Hopkins University, where he works. He has already received \$50,000 from Merck and was awaiting funds from Wyeth Lederle.

Dr. Halsey also participated in the rotavirus working group of the ACIP.

Also, Dr. Halsey was the Chair of the Committee on Infectious Diseases and representative of the American Academy of Pediatrics which, in conjunction with the CDC, sets and advertises the recommendations for schedules and dosages of immunizations. Dr. Halsey was granted a waiver by the FDA for participation in the VRBPAC.

He participated during the morning session and then recused himself at the beginning of the afternoon session due to conflicts that were not disclosed in the minutes of the meeting.

Finally, Dr. Halsey's employer, Johns Hopkins University, is also the employer of Dr. Clements-Mann, who was excluded from the discussions.

b.) Dr. Yvonne Maldonado: No apparent conflicts were listed for Dr. Maldonado.

c.) Dr. John Modlin: At the time of the "RotaShield" approval meeting, Dr. Modlin owned approximately \$26,000 of stock in Merck, an affected company.

He has also served on Merck's Immunization Advisory Board from 1996 to the present. These financial interests were waived and he was allowed to participate

extensively in the meeting although, as a consultant, he was not allowed to vote. Also, Dr. Modlin was at the time the Chairman of the ACIP and its rotavirus working group.

5. Balanced representation:

As previously discussed, the statutory requirement of balanced representation is one of the most controversial provisions of the FACA. The FDA has interpreted "balance" as diversity of geography, ethnicity, disciplines and gender. While it is questionable whether this standard guarantees the balance of points of view represented expressly required by the statute, it was interesting to see the high concentration of professors in pediatrics represented on the VRBPAC committee, particularly during the "RotaShield" discussion (Dr. Ferrieri, Dr. Karzon, Dr. Edwards, Dr. Modlin, and Dr. Halsey). Also, two of the voting members work for Vanderbilt University (Dr. Edwards & Dr. Karzon), while one member, Dr. Clements-Mann (who, although excluded from voting, was able to participate in the open public hearing part of the meeting) and Dr. Halsey, both came from Johns Hopkins University. Two of the voting members (Dr. Broome and Dr.

John Modlin, M.D., Chairman

Dr. Modlin has a conflict with Merck as described in this report.

Chinh T. Le, M.D.

Dr. Le has conflicts with Wyeth Lederle and SmithKline-Beecham.

David W. Fleming, M.D

Roger I. Glass, M.D., Ph.D.

Joseph S. Bresee, M.D.

Centers for Disease Control and Prevention

National Center of Viral and Rickettsial Diseases

National Center for Infectious Diseases

Margaret Rennels, M. D.

Department of Pediatrics, University of Maryland

Her employer's website states that she participated in virtually all phases of the testing of the licensed rotavirus vaccine.

Also, she is affiliated with the U.S. Rotavirus Efficacy Group

Richard Zimmerman, M.D.

American Academy of Family Physicians (AAFP)

The AAFP has conflicts with numerous vaccine manufacturers as described in this report.

Neal A. Halsey, M.D.

American Academy of Pediatrics

At the time of the rotavirus approval meeting, Dr. Halsey was seeking start-up funds from most of the vaccine manufacturers for the establishment of an institute for vaccine safety at Johns Hopkins University, where he works. He has already received \$50,000 from Merck and was awaiting funds from Wyeth Lederle. He has received frequent reimbursements for travel expenses and honoraria from companies such as Merck. Dr. Halsey serves on the advisory board to the Immunization Action Coalition, an advocacy group funded by vaccine makers including: Aventis Pasteur, Chiron Corporation, Glaxo Wellcome, Merck & Co., Nabi, North American Vaccine, SmithKline-Beecham, and Wyeth-Lederle Vaccines.

Peter Paradiso, Ph.D.

Lederle-Praxis Biologicals Division

Wyeth-Lederle Vaccines and Pediatrics

Florian Schodel, M.D.

Office for Clinical Vaccine Research

Merck Research Labs

ACIP is not Fairly Balanced in Terms of the Points of View Represented

According to section 5 of FACA, membership on an advisory committee must be "fairly balanced in terms of points of view represented and the functions to be performed . . ." and the advice and recommendations of the advisory committee cannot be